ClinicalTrials.gov
Protocol Registration System
User's Guide
March 2004 (revised)

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National Institute of Mental Health (NIMH)
Overview

What is *ClinicalTrials.gov*?

ClinicalTrials.gov provides patients, family members, health care professionals, and members of the public easy access to information on clinical trials for a wide range of diseases and conditions. The U.S. National Library of Medicine (NLM) has developed this site in collaboration with all NIH Institutes and the Food and Drug Administration (FDA). See http://www.clinicaltrials.gov/ct/info/about for the complete background on the development of the ClinicalTrials.gov database. The NIMH encourages the listing of all of the appropriate clinical trials that it sponsors in *ClinicalTrials.gov* and has developed this User Guide manual to assist investigators and facilitate that process.

NIH and NIMH are firmly committed to their mission of improving the lives and health of the public. Through research all people can benefit from the knowledge compiled through testing medications, procedures, vaccines, behaviors, and devices from clinical trials.

Is it necessary to seek IRB approval for information listed in *ClinicalTrials.gov* records?

Please refer to Section L of the FDA's "Guidance for Industry Program on Clinical Trials for Serious or Life-Threatening Diseases and Conditions," which states:

"L. Is Institutional Review Board preapproval of the protocol listing required?

No. Section 113 of the Modernization Act does not require prior IRB approval when submitting this information to the Clinical Trials Data Bank. Current FDA guidance recommends that IRB review of listings need not occur when, as here, the system format limits the information provided to basic information, such as title, purpose of the study, protocol summary, basic eligibility criteria, study site locations, and how to contact the site for further information. 11"
http://www.fda.gov/cder/guidance/4856fnl.htm

If your trial becomes listed in *ClinicalTrials.gov*, the NIMH web site (http://www.nimh.nih.gov) will provide a pointer to your study through its Clinical Trials information page http://156.40.208.53/Studies/index.cfm in concert with the appropriate mental health topic in order to further facilitate the public's understanding of ongoing studies of mental illnesses and related topics.

Protocol Registration System (PRS)

The Protocol Registration System (PRS) is a Web-based tool developed by the National Library of Medicine for submitting clinical trials information to *ClinicalTrials.gov*. Records submitted through PRS (http://register.clinicaltrials.gov) are available to the public at http://clinicaltrials.gov

PRS users enter information about their clinical trials, ensuring that the information is correct, easily understood by members of the public, and updated in a timely manner. The *ClinicalTrials.gov* team maintains PRS and the *ClinicalTrials.gov* site and may make minor corrections to trial records.

The following information is for NIMH investigators and study personnel who want to submit summary information about their trials to be listed in the *ClinicalTrials.gov* database. You will find details about whom to contact and what the process is for getting started and how your trial can be listed in the database.

Administrative Procedures

User Definitions:

NIMH *ClinicalTrials.gov* Liaison (Nancy Oleksa, e-mail: noleksa@mail.nih.gov)
NIMH Contractor (Christine Love, email: clove@aspensys.com)
PRS User

Process:

1. NIMH Liaison alerts NIMH Contractor of a new grantee.

2. Using the grantee information, the NIMH Contractor contacts the User and requests that he/she open his/her record and, following the PRS Data Element Definitions (p. 11), provide data for the following mandatory fields:

Brief Title	Study Design
IND Protocol (if applicable)	Intervention Type
IND Grantor (if applicable)	Intervention Name
IND Number (if applicable)	Condition(s)
Brief Summary	Eligibility Criteria
Detailed Description	Gender
Study Phase	Age Limits
Study Type	Accepts Healthy Volunteers?
Overall Study Status	Contact Information

On occasion, a single clinical trial is conducted at different sites under different Principal Investigators (PIs). In order to avoid the duplication of records in the *ClinicalTrials.gov* system, NIMH has determined that all information regarding multi-site trials will be obtained from a central contact person. This person will be identified by the Project Officer for the trial and will be responsible for updating the trial record as needed. PIs who are involved in a multi-site trial will be given the email address, phone number, or fax number of their central contact. PIs will be responsible for sending the central contact any updates that are related to their site.

3. User changes record status to [Complete] and the PRS automatically notifies the NIMH Liaison.

4. NIMH Liaison reviews, approves, and releases currently recruiting records to *ClinicalTrials.gov*. Records whose trials are not recruiting will remain unreleased until their status changes.

Please note: Records are not released until all data has been reviewed. NIMH reserves the right to edit data entered by the User

5. NLM publishes the record within 2-5 days of release.

6. The NIMH Contractor will conduct semi-annual verifications of all trial records. Central Contacts will be contacted via email and asked to go into ClinicalTrials.gov to verify the accuracy of their record. Once a record has been completed, the NIMH Contractor will request that the Central Contact add publication information to the record as it becomes available.

PRS User Responsibilities

PRS users provide and maintain information about their clinical trials by entering information into PRS and ensuring that the information is correct, easy to understand, and updated in a timely manner.

Through PRS, a user may:

Log-in to *ClinicalTrials.gov*.

Enter information regarding clinical trials.

Modify a record.

View a record.

Change a password.

Preview a record as a *ClinicalTrials.gov* page.

Complete and submit the trial data for approval.

Procedures for PRS Users

Logging In and Out of PRS:

1. Go to http://register.Clinicaltrials.gov to enter PRS.

2. Complete the three log-in fields
   A. Organization: NIMH
   B. User name: user login name*
   C. Password: user password (case-sensitive)*

3. Click [Login] and to get to the **Main Menu** of PRS.

4. To log out of PRS, select [Logout] from the **Main Menu** screen.

* *For security reasons, users are asked to please change their password after logging in the first time.*

Creating a Record:

1. Click [Create] from the **Main Menu** screen.

2. Enter the Unique Protocol ID and Brief Title for your record on the **Create New Protocol Record** screen.

3. Click [Continue] to save data and proceed to the next screen. Repeat data entry and [Continue] for successive screens.

4. After clicking [Continue] on the final data entry screen, clink [OK] on the **Study Completed** screen.

Tips:

The data entry screens contain text boxes, radio buttons, pull down menus, and other tools to facilitate data entry.

Data screens are clustered by topic for each clinical trial. These include: Title, Sponsor, Summary, Status, Design, Interventions, Conditions, Eligibility, Locations, Citations, and Links.

Field definitions and examples can be viewed by clicking on the links associated with each field name.

A record may be completed during a single session or modified and saved for completion during later sessions.

Modifying Records:

1. Click [Modify] on the **Main Menu**.

2. On the **Select Protocol Record-Edit** screen, use the drop-down list under **Search** to choose the appropriate search information. If you want to search all records, check each option under **Records to include in the list** and click [OK] at the bottom of the screen.

3. Locate the data fields to be modified on the **Edit Protocol Screen**, click on the corresponding [Edit] for that field, and make necessary changes.

4. Click [Continue] to save data and proceed to the next screen. Repeat data entry and [Continue] for successive screens.

5. After clicking [Continue] on the final data entry screen (**Links**), click [OK] on the **Study Completed** screen.

Viewing Records:

1. Click [View] on the **Main Menu**.

2. On the **Select Protocol Record-Edit** screen, use the drop-down list under **Search** to choose the appropriate search record. If you want to search all records, check each option under **Records to include in the list** and click [OK] at the bottom of the screen.

3. Click [View] next to record to be displayed.

*** View Protocol Record** is read-only. User must choose Edit from the Main Menu to modify record information.

Previewing Records as They Appear on *ClinicalTrials.gov:*

1. Click [Modify] on the **Main Menu**.

2. Click [Edit] next to the record to be previewed

3. Click [Preview] to see the record displayed similar to how it appears on *ClinicalTrials.gov.*

4. Click [Continue] to return to the **Edit Protocol Record** screen.

Changing Your Password:

1. Click [Change password] on the **Main Menu**.

2. Enter:
   Old password*
   New password
   New password again for verification

3. Click [Change Password] to save new password.

*Contact Nancy if the password is forgotten or lost.

Completing and Submitting the Trial for Approval:

1. If modifying an existing record, click [Modify] from the **Main Menu**, then click the Edit link to the left of the record you wish to complete.

2. Proceed to the **Edit Protocol** Screen.

3. PRS automatically checks the data for any errors or potential problems. There are two types of messages that may be displayed for fields in the record:
   A. Error: a problem has been found with the record that MUST be corrected. The record will not be released to *Clinicaltrials.gov* until the error is resolved.
   B. Note: a potential problem has been found, that should be reviewed. The record can be released to *Clinicaltrials.gov* with a "Note."

4. After all available information has been entered into a record and there are no errors:
   A. Click on the [Change Status] link or the record.
   B. Click the Completed check box on the screen (this will generate an email to Nancy).
   C. Type any comments in the text that you wish to have Nancy review when viewing the record.
   D. Click [OK] to save the status change, or [Cancel] to retain the original status.

Nancy will then review the clinical trial record. If no changes are needed, the record will be approved and sent to *ClinicalTrials.gov*.

Attachment 1: Sample PI Contact E-Mail

Date

Dear NIMH Grantee:

I would like to introduce myself as the NIMH administrator for *ClinicalTrials.gov*, an online database developed and maintained by NIH's National Library of Medicine (NLM). *ClinicalTrials.gov* informs patients, family members, healthcare providers, and the general public about ongoing clinical research and affords NIH the opportunity to highlight its activities. The web site for this database is located at http://www.clinicaltrials.gov.

You are receiving this letter because your NIMH-sponsored trial, Trial title, has been identified for inclusion in *ClinicalTrials.gov*. For the purpose of this database, a clinical trial/clinical research is defined as a research study in human volunteers to answer specific health questions and may involve an interventional, observational, or natural history study.

We would appreciate it if you would enter information about your trial into the *ClinicalTrials.gov* database. Instructions for how to do this are included at the end of this letter. Christine Love of Aspen Systems Corporation is serving as NIMH's contractor and will be happy to provide any assistance you may need. Ms. Love can be reached at 301-519-5683 or update@clinicaltrials.gov. If you are not the appropriate contact for this information, please send the name and e-mail address of the person who will be responsible for entering and updating your study description to update@clinicaltrials.gov.

NIMH is committed to providing information about its trials to the public, and we appreciate your cooperation with our efforts. Please contact Ms. Love or me with any questions regarding this request. I can be reached at noleksa@mail.nih.gov.

Sincerely,
Nancy Oleksa
NIMH Liaison for ClinicalTrials.gov

Christine N. Love
NIMH Clinical Trials Records Coordinator
National Library of Medicine's
Clinical Information Services
Rockville, MD
301-519-6353

Entering Your Trial Information:
Provide information about your trial by logging into the Protocol Registration System (PRS) and following these instructions:
1. Visit this web site: https://register.clinicaltrials.gov/
2. Log in with the following information:
Organization: NIMH
User Name: jsmith
Password: jsmith
3. From the Main Menu screen, select Create.
4. Enter Grant number as the Unique Protocol ID.
5. Enter a Brief (lay) Title and select continue.
6. Provide as much information as possible in the available fields.
    Include both a **brief summary** and **detailed description**.
    List both **inclusion** and **exclusion criteria** in the eligibility criteria field.
4. When you have completed the record, select Next Action: Complete.

For directions and further information, refer to the NIMH User Guide http://www.nimh.nih.gov/studies/ctgovuserguide.pdf a document listing specific NIMH requirements.

Please send an email to update@clinicaltrials.gov once you have completed the record, so that I can release your record to *ClinicalTrials.gov*. After your record has been completed, I may contact you to request further information. Your record may be edited in order to maintain consistency in format and content across all NIMH records.

Attachment 2: Data Element Definitions

1. Titles and Background Information

Organization's Unique Protocol ID
Submission: Required
Definition: Identification number assigned to the protocol by the sponsoring organization, usually an accession number or a variation of a grant number. Multiple studies conducted under the same grant must each have a unique number. Grants with a prefix of P50 indicate a project that may contain many sub-projects where maybe two of which (say 2 & 5) involve human subjects of clinical trials.
Example: IA0014; MH42931A

Secondary IDs
Submission: Optional
Definition: Other identification numbers assigned to the protocol, including any applicable NIH grant numbers. Provide up to 5 Secondary ID Numbers. Example: 5 R01-MH42931A; MH56224

Brief Title
Submission: Required
Definition: Protocol title intended for the lay public, usually found on line one of the grant application.
Example: Preventing the Return of Depression in Elderly Patients

Official Title
Submission: Optional
Definition: Official name of the protocol provided by the principal investigator or sponsor.
Example: Maintenance Therapies in Late-Life Depression

Additional Information

IRB Approved?
Definition: Indicate if the protocol has received Institutional Review Board (IRB) approval. Select Yes/No.

Medicare: Organization is Deemed?
Definition: Trials funded by NIH, CDC, AHRQ, HCFA, DOD, and VA, trials conducted at NCI cancer centers, and all trials of patients that are either conducted under an Investigational New Drug Application (IND) or are exempt from having an IND under 21 CFR 312.2(b)(1) are considered Medicare deemed. See Medicare Coverage Policy ~ Clinical Trials: Final National Coverage Decision.

Medicare: Study Meets Requirements?
Definition: The subject of the trial must evaluate an item or service that falls within a Medicare benefit category and is not statutorily excluded from coverage. See Medicare Coverage Policy ~ Clinical Trials: Final National Coverage Decision.

2. Investigational New Drug Application (IND) Information: Complete the following only if the protocol requires and Investigational New Drug Application (IND). (*Will not be made public- for administrative purposes only*.)

IND Protocol?
Submission: Required
Definition: Indicate if the protocol is being conducted under an Investigational New Drug Application (IND). If not, select "No" and continue. (*Will not be made public- for administrative purposes only*.)

IND Grantor
Submission: Required
Definition: FDA center to which the IND was submitted, i.e., Center for Drug Evaluation and Research (CDER) or Center for Biologics Evaluation and Research (CBER). Select one. (*Will not be made public- for administrative purposes only*.)

IND Number
Submission: Required
Definition: Number assigned to an Investigational New Drug Application (IND). If not yet received, use "Not Yet Assigned". (*Will not be made public- for administrative purposes only*.)
Example: 58-484

3. Sponsors

Sponsor
Submission: Required
Definition: Name of sponsoring organization who takes responsibility for and initiates a clinical investigation.
Example: National Institute of Mental Health (NIMH)

Collaborators
Submission: Optional
Definition: Full names of organizations co-sponsoring and/or providing financial support for the protocol. Provide up to 10 full names of collaborating organizations.

4. Study Description

Brief Summary
Submission: Required
Definition: Short description of the purpose of the protocol intended for the lay public.
Example: The purpose of this study is to assess the effectiveness and safety of both St. John's wort and citalopram, each compared to a placebo, for the treatment of minor depression.

Detailed Description
Submission: Optional
Definition: Technical description of the protocol for health professionals, including information such as methodology and rationale, not already contained in other fields.
Example: Minor depression is highly prevalent, causes substantial morbidity and disability, presents a serious risk factor for the development of major depressive disorder, yet is under recognized and under treated. Researchers have determined that patients with minor depression frequently seek treatment from general practitioners and are often treated with prescription antidepressants. There is a need to

evaluate the effectiveness of St. John's wort in the management of minor depression. If the proposed study demonstrates the efficacy of St. John's wort and/or citalopram, it will suggest treatment paradigms that can be tested and applied in primary care settings.
At Screen Visit, Week 12, and Week 20, patients undergo a complete blood count with differential and other routine laboratory tests. Patients who meet screening criteria enter a 2-week washout period (or for fluoxetine, a 4-week washout period) during which no psychotropic medication is permitted. Participants are assigned randomly to one of three treatment arms in which St. John's wort, citalopram, or placebo is given for a 12-week acute treatment phase. Participants are seen at screening, during the washout period, at baseline, and every 2 weeks thereafter for the course of the study. Participants that meet criteria for response (50 percent or greater reduction in Inventory for Depressive Symptoms - Clinicians [IDS-C]) at Week 12 continue to take their originally assigned double-blind medication for up to 26 weeks. At Week 12, nonresponders to placebo are crossed over to one of the two active treatments. Patients who remain nonresponders to that active treatment are crossed over to the alternative active treatment, with the investigator maintaining blind status.

5. Status

Study Phase
Submission: Required
Definition: Phase of the Investigation. Select only one.

Phase 1: includes initial studies to determine the metabolism and pharmacologic actions of drugs in humans, the side effects associated with increasing doses, and to gain early evidence of effectiveness; may include health participants and/or patients

Phase 1/Phase 2

Phase 2: includes controlled clinical studies conducted to evaluate the effectiveness of the drug for a particular indication or indications in patients with the disease or condition under the study and to determine the common short-term effects and risks

Phase 2/Phase 3

Phase 3: includes expanded controlled and uncontrolled trials after preliminary evidence suggesting effectiveness of the drug has been obtained, and are intended to gather additional information to evaluate the overall benefit-risk relationship of the drug and provide an adequate basis for physical labeling

Phase 4: post-marketing studies to delineate additional information including the drug's risks, benefits, and optimal use

N/A: IND studies must not use this option

Study Type
Submission: Required
Definition: Nature of the investigation. Select one.

- Interventional: experimental studies in humans to investigate the safety and/or efficacy of a drug, gene therapy, vaccine, behavior, device, or procedure.
- Observational: studies in humans that record specific events occurring in a defined population without any intervention by the researcher, such as natural history, screening, and psychosocial studies.

Overall Study Status
Submission: Required
Definition: Overall protocol accrual activity for the protocol. Select one.

- Not yet recruiting: the protocol is not yet ret recruiting and enrolling participants
- Recruiting: the protocol is actively recruiting and enrolling participants
- No longer recruiting: the protocol is not recruiting or enrolling participants
- Complete: the protocol is no longer recruiting. Data analysis is complete.
- Suspended: recruiting or enrolling participants has halted but may potentially resume
- Terminated: recruiting or enrolling participants has halted and will not resume

Verification Date
Submission: Required
Definition: Date the protocol information, including status, was verified, whether changes or made or not.

Start Date
Submission: Optional
Definition: Date that the protocol begins.

Completion Date
Submission: Optional
Definition: Expected or actual completion date of the protocol.

6. Study Design

Study Type (Interventional)
Submission: Required
Definition: Primary investigative techniques used in the protocol. Select the most appropriate term describing the protocol from each of six categories: Purpose, Allocation, Masking, Control, Assignment, and Endpoint.

Purpose: reason for the protocol

- **Treatment:** protocol designed to evaluate one or more interventions for treating a disease, syndrome, or condition
- **Prevention:** protocol designed to assess one or more interventions aimed at preventing the development of a specific disease or health condition
- **Diagnosis:** protocol designed to evaluate one or more interventions aimed at identifying a disease or health condition
- **Educational/Counseling/Training:** protocol designed to assess one or more interventions in an educational, counseling, or training environment

Allocation: participant selection

- Randomized Controlled Trial: participants are assigned to intervention groups by chance
- Nonrandomized Trial: participants are expressly assigned to intervention groups

Masking: knowledge of intervention assignments

- Open: no masking is used. All involved know the identity of the intervention assignment
- Single Blind: participants are unaware of the intervention assignment; investigators are aware.
- Double Blind: both participants and investigator s are unaware of the intervention assignment

Control: the nature of the intervention control

- Placebo: participants may receive **placebo only throughout** the course of the protocol
- Active: participants may receive some form of treatment (e.g., standard treatment) in place of the intervention under investigation
- None: no controls are used
- Historical: the control consists of results from past studies
- Dose Comparison: participants may receive one of several doses of the intervention

Assignment: intervention assignments

- Single or Group: all participants receive the **same** intervention throughout the protocol
- Parallel: participants receive **some** intervention throughout the protocol
- Cross-over: participants may receive **different** interventions sequentially during the protocol
- Factorial: participants may receive no intervention, **some** intervention, or **multiple** interventions **simultaneously**

Endpoint: overall outcome that the protocol is designed to evaluate. Select one.

- Safety: shows the drug is safe under conditions or proposed use.
- Efficacy: measure of an intervention's influence on a disease or health condition.
- Safety/Efficacy
- Bio-equivalence: scientific basis for comparing generic and brand name drugs.
- Bio-availability: rate and extent to which a drug is absorbed or otherwise available to the treatment site in the body
- Pharmacokinetics: the action of a drug in the body over a period of time including the process of absorption, distribution and localization in tissue, biotransformation, and excretion of the compound
- Pharmacokinetics: action of drugs in living systems
- Pharmacokinetics/Pharmacodynamics

Study Type (Observational)

Definition: Primary investigative techniques used in an observational protocol. Select the **most appropriate** term describing the protocol from each of the four categories:

Purpose, Duration, Selection, and Timing

Purpose: reason for the protocol

- Natural History: protocol designed to investigate a disease or condition through observation under natural conditions (i.e., without intervention)
- Screening: protocol designed to assess or examine persons or groups in a systematic way to identify specific markers or characteristics (e.g., for eligibility for further evaluation)
- Psychosocial: protocol designed to observe the psychosocial impact of natural events

Duration: length of protocol

- Longitudinal: studies in which participants are evaluated over long periods of
- time, typically months or years
- Cross-sectional: studies in which participants are evaluated over short periods
- of time, typically up to 10 weeks

Selection: sample selection

- Convenience Sample; participants or populations are selected due to ease of recruitment
- Defined Population: participants or populations are selected based on predefined criteria
- Random Sample: participants or populations are selected by chance

- Case Control: participants or populations are selected to match the control participants or populations in all relevant factors excepts for the disease; only the participants or populations have the disease

Timing: time of protocol
- Retrospective: a protocol that observes events in the past
- Prospective: a protocol that observed events in real time (may occur in the future)
- Both: a protocol that combined retrospective and prospective observation

7. Conditions and Keywords

Conditions
Submission: Required
Definition: Primary diseases or conditions being studies, using the National Library of Medicine's Medical Subject Headings (MeSH) controlled vocabulary. The conditions are used to index studies in *ClinicalTrials.gov.* Select up to five disease or condition terms from the following MeSH categories: Diseases (c), Behavior and Behavior Modification (F01), and Mental Disorders (F03).

Keywords
Submission: Optional
Definition: Words or phrases that best describe the protocol. Keywords help users find studies in the database. Use NLM's Medical Subject Heading (MeSH) controlled vocabulary terms where appropriate. Be as specific and precise as possible. Avoid acronyms and abbreviations.

8. Interventions

Submission: Required
Definitions: Primary interventions being studied. Provide specific name and type for each intervention (up to 10 items).

Intervention Type: select one per intervention
-Drug
-Gene Transfer- including gene transfer and recombinant DNA
-Vaccine
-Behavior
-Device
-Procedure

Intervention Name
Definition: generic name of the precise intervention being studies.
Examples:
Zidovudine (drug)
Exercise (behavior)

9. Eligibility

Eligibility Criteria
Submission: Required
Definition: Summary criteria for participant selection
Example:
Inclusion Criteria:
- Clinical diagnosis of Alzheimer's Disease
- Must be able to swallow tablets

Exclusion Criteria:

- Current alcohol or drug abuse
- Thyroid disease

Gender
Submission: Required
Definition: Physical gender of individuals who may participate in the protocol. Select one.

- Both: both female and male participants are being studied
- Female: only female participants are being studied
- Male: only male participants are being studied

Age Limits

Minimum Age
Submission: Required
Definition: Minimum age of participants. Provide a number and select a unit of time (years, months, weeks, days, hours, or minutes). Select "N/A (No limit)" if no minimum age is indicated.

Maximum Age
Submission: Required
Definition: Maximum age of participants. Provide a number and select a unit of time (years, months, weeks, days, hours, or minutes). Select "N/A (No limit)" if no maximum age is indicated.

Acceptable Participants

Accepts Healthy Volunteers?
Submission: Required
Definition: Indicate if persons who have not had the condition(s) being studied or otherwise related conditions or symptoms, as specified in the eligibility requirements, may participate in the study. Select Yes/No.

Accepts Patients?
Definition: Indicate if persons who have or had the condition(s) being studied or otherwise specified in the eligibility requirements (e.g., specific symptoms), may participate in the study. Select Yes/No.

Expected Total Enrollment
Submission: Optional
Definition: Estimated number of participants to be studied

10. Protocol Location, Contact and Investigator Information

Multiple locations may be specified. Location is composed of the following fields:

Facility
Submission: Required
-Name: Full name of the organization where the protocol is being conducted
Examples: UCLA Eye Institute; Springfield Memorial Hospital
-City
-State/Province
-Postal Code
-Country

Recruitment Status: protocol accrual activity at the facility. Select one.
Submission: Required (if Overall Status is "Recruiting")

- Not yet recruiting: participants are not yet being recruited or enrolled
- Recruiting: participants are currently being recruited or enrolled
- No longer recruiting: participants are no longer being recruited or enrolled
- Completed: participants are no longer being recruited; data analysis is complete
- Suspended: recruiting or enrolling participants has halted but potentially will resume
- Terminated: recruiting or enrolling participants has halted and will not resume

Facility Contact
Submission: Required (If Overall Status is recruiting)

- First Name
- Middle Name
- Last Name
- Degree
- Phone: office phone of the facility contact person. Use the format 123-456-7890 within the United States and Canada. Otherwise, provide the country code.
- Ext: phone extension, if needed
- Email: electronic mail address of the facility contact person

Facility Contact Backup
Submission: Optional
Definition: Person to contact if Facility Contact is not available (i.e., a second contact person).

Investigators (at the protocol location)
Submission: Optional

- First Name
- Middle Initial
- Last Name
- Degrees
- Role: Principal Investigator or Sub-Investigator (pick one)

Central Contact
Submission: Required (if a Facility Contact is not provided)
Definition: Person providing centralized, coordinated recruitment information for the entire study.

- First Name
- Middle Initial
- Last Name
- Degree
- Phone: office phone of the facility contact person. Use the format 123-456-7890 within the United States and Canada. Otherwise, provide the country code.
- Ext: phone extension, if needed
- Email: electronic mail address of the facility contact person

Central Contact Backup
Submission: Optional
Definition: Person to contact if Central Contact is not available.

Overall Study Officials
Submission: Optional
Definition: Person(s) responsible for the overall scientific leadership of the protocol.

- First Name
- Middle Initial
- Last Name
- Degree

- Official's Role: Position or function of the official. Select one (Study Chair/Study Director/Principal Investigator).
- Organizational Affiliation: Full name of the official's organization.

11. Related Information

References
Submission: Optional
Definition: Citations to publications related to the protocol: background and/or results. Provide either the unique PubMed Identifier (**PMID**) of an article or enter the full bibliographic citation.

MEDLINE PMID
Definition: unique PubMed Identifier (**PMID**) for the citation
Example: **PMID**: 12000823

Citation
Definition: bibliographic reference in **NLM's MEDLINE** format
Example: Apolone G, Mosconi P, La Vecchia C. Post-traumatic stress disorder. N Engl J Med. 2002 May 9;346(19):1495-8; discussion 1495-8.